MAY 0 9 2002

K020547

Ohmeda Medical Giraffe® Incubator
510(k) Summary

Submitter Information

Alberto F. Profumo, RAC
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Laurel, MD 21046-1801
Tel. (410) 888-5104
Summary prepared on 2/12/2002

Device Name(s)

Classification Name:
- Neonatal Incubator

Common Name:
- Incubator

Proprietary Name:
- Ohmeda Medical Giraffe™ Incubator with Optional Servo Control Oxygen System

Predicate Device Information

The Giraffe Incubator is substantially equivalent to the following Class II devices:

Device	Last 510(k) Number
Ohmeda Medical Giraffe Incubator (original)	K010222
Drager Incubator 8000 IC	K954204
Isolette Infant Incubator Model C2HS	K001242

Product Description

The Ohmeda Medical Giraffe Incubator is an infant bed which provides thermal support for infants who are unable to provide for their own heat requirements. The device maintains the infant's temperature by circulating heated air within the enclosed bed compartment. The operator may select either the air or skin temperature control method. Depending on the control method selected, heat is regulated based on either the air temperature or the infant's skin temperature compared to the operator selected control temperature. Physical access to the patient is obtained through the side portholes or by opening one of the side doors.

The optional Giraffe Servo Controlled Oxygen System is a fully integrated option available on the Giraffe Incubator. The Servo Controlled Oxygen System is capable of oxygenating the entire infant compartment at oxygen concentrations of 21-65% by volume. The device uses fuel cell type sensors that generate specific voltages depending on the oxygen concentrations they contact. The microprocessor stores the sensor output and compares it with the value corresponding to the concentration set by the operator. The valves that supply oxygen to the infant compartment are opened and closed as necessary to maintain the oxygen concentration at the set value. Fluctuations in fuel cell performance due to temperature and humidity are compensated for by the microprocessor.

Indications for Use

The Giraffe Incubator is an infant incubator. Incubators provide heat in a controlled manner to neonates who are unable to thermo-regulate based on their own physiology. They achieve this by providing an enclosed temperature controlled environment for the infant. This device may incorporate a Servo Controlled Oxygen Delivery System. This is indicated to provide a stable oxygen concentration within the infant compartment at the value set by the operator (21-65%).

Assessment of Technological Characteristics

The technological characteristics of the Giraffe Incubator are similar to those of predicate devices and do not raise new safety or effectiveness issues.

Performance Data

Since care of newborns in incubators, with or without supplemental oxygen, is a well established clinical practice, Ohmeda submits that clinical or animal testing to demonstrate safety and effectiveness is not necessary. The product was subject to extensive bench testing, the software was validated, and, to the best of Ohmeda Medical's knowledge, the requirements of 21 CFR 820, Subpart C – Design Controls – were satisfied.

Sterilization Information

The Giraffe™ Incubator is not intended to be sterilized. Cleaning and disinfection instructions can be found in the Operations and Maintenance Manual.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 0 9 2002

Mr. Alberto F. Profumo
Director, Product Assurance
Ohmeda Medical
8880 Gorman Road
Laural, Maryland 20723

Re: K020547
Trade/Device Name: Giraffe™ Incubator
Regulation Number: 880.5400
Regulation Name: Incubator, Neonatal
Regulatory Class: II
Product Code: FMZ
Dated: February 18, 2002
Received: February 19, 2002

Dear Mr. Profumo:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618 . Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Susan Runner

for Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K020547

Device Name: Giraffe™ Incubator

Indications for Use:

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(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21 CDR 801.109)

OR

Over-The Counter Use ____
(Optional Format 1-2-96)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K020547